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piezosteril 6 - piezolight 6

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1. INTENDED USE

This is a Medical device, or a medical device accessory for professional use by Dentists, assisted by authorised office personnel.
The device is intended for use on Dental Units complying with the 93/42/EEC Directive and subsequent additions and amendments, complying with the IEC 60601-1 standard (III ed.) and installed in locations meeting the standards in force for locations for medical purposes and with an electrical plant system that complies with the IEC 60364-7-710 standard.

2. IMPORTANT WARNINGS

Before using the device read the instructions in this manual carefully. The use of the device must respect the instructions provided.
For the correct interpretation of the indications in this manual the Italian text is binding.

- The device is not suitable for use with blends of inflammable anaesthetics and oxygen or nitrous oxide.
- The instrument is provided in a non-sterile state. Before use, see to its suitable cleaning and disinfection.
- Use of electrically-powered devices may interfere with the operation of active implantable devices such as pacemakers or other active devices. In case of doubt regarding the treatment of patients with such devices, consult a cardiology expert or another competent medical institute.
- During use of the device dust and fragments from the patient's oral cavity or from the same device may be projected into the environment (organic and inorganic powders, fragments of the inserts, potentially infectious biological materials).
    - Protect the patient, when possible, using a dental dam.
    - Instruct the patient to breathe through the nose in cases where the dam is not applicable.
    - Medical personnel must put on suitable personal protection equipment.
- Suitably cool the surgical field during use.
- In case of visible damage, the emission of unusual noises and/or vibrations or if overheating is noticed, do not use the device and call authorised technical service assistance.
- The scalers must be used exclusively with the inserts supplied, with original spare parts or with inserts approved by the manufacturer.
- Before use, check that the inserts are secured in place.
- Do not use worn or damaged inserts. Handle the inserts carefully wearing protective gloves.
- Use only inserts bearing the CE marking under Directive 93/42/EEC and subsequent additions and amendments, made of biocompatible materials in accordance with the ISO 10993-1 standard.
- Use only original spare parts and accessories, or those authorised by the manufacturer.
- Do not change the structure of the inserts by bending or filing them.
- Do not use the handpiece on metal or ceramic articles. The high frequency oscillations can damage them.
- The inserts can be particularly pointed and sharp. To avoid accidental cuts or injuries, take care when the inserts are mounted on the handpiece and remove them after use.
- Make sure that the surgical area cooling flow is present during operation. In the absence of cooling, suspend use of the device and contact the authorized technical support service.
- If saline is used as a coolant, before removing the handpiece, it is necessary to drain the water for at least 20 seconds in order to rinse the ducts of the handpiece and the water circuit.
- LED radiation: do not stare into beam or view directly with optical instruments.

The manufacturer will not be held responsible regarding safety, reliability or performance of the device if:

- The essential requirements for the location, detailed in the Dental Unit User Manual are not respected;
- The assembly, the additions, the adjustments, the calibrations and/or the repairs are not performed by authorised technical service personnel;
- If modifications, tampering, incorrect maintenance have been performed, or incompatible and/or non-original spare parts have been used on the device;
- The device is not used in compliance with the use instructions and its intended use.

3. SYMBOLS

	Symbol to call the attention to other information found in the equipment User Manual.
	Symbol corresponding to “TYPE B PART APPLIED” according to IEC 60601-1. Indicates a protection grade against direct and indirect contacts.
	Part that may be sterilised in an autoclave.
	Mark of Compliance with the 93/42/EEC Directive “MEDICAL DEVICES” and subsequent additions and amendments.
	Symbol for disposal pursuant to the 2002/95/EC, 2002/96/EC, 2003/108/EC Directives.

4. TECHNICAL SPECIFICATIONS

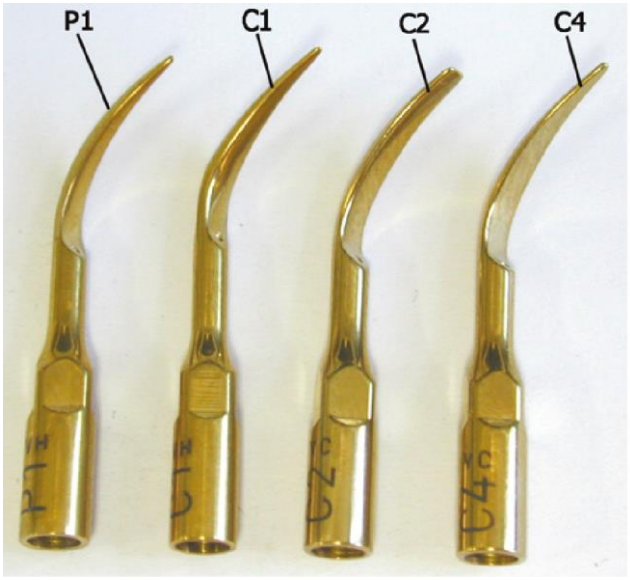
	piezosteril 6	piezolight 6
Rated power	32 VDC	
Max Electrical power absorbed	15 W	
Working frequency	25.000 ÷ 32.000 Hz	
Intermittent Operation	20 min of work - 10 min of rest	
Water Supply	90 ÷ 140 kPa (0,9 ÷ 1,4 bar)	
Classification	Class IIa (Directive 93/42 EEC and subsequent additions and amendments) Class II type B (IEC 60601-1)	
LED Illumination		3500 K - 20000 mlm λ 400 ÷ 600 nm P_{max} < 1 mW
Applicable regulations	IEC 60601-1 – IEC 60601-2 - ISO 10993-1 IEC 62471 - ISO 22374	

For the correct operation of the device it must be connected to the specific power supply and electronic control circuits, designed by the manufacturer, by way of suitable connection supply tubing.
The manufacturer promises to provide, upon request, wiring diagrams, component parts lists, calibration instructions or any other information that may be needed by authorised technical service assistance personnel.
The manufacturer reserves the right to bring about modifications at any moment without notice.

5. CONNECTION TO THE POWER SUPPLY INSTRUMENT TUBING

The scaler must be fully engaged on its power cord. This can be achieved by pushing it in.
Ensure that the coupling surfaces are clean and dry.
Do not unplug the scaler from the cord while it is operating.

6. MOUNTING THE INSERTS



The scalers must be used exclusively with the inserts supplied, with original spare parts or with inserts approved by the manufacturer.
They must be screwed and tightened using the appropriate torque wrench only.
In the handpiece marked with Ⓢ use exclusively the inserts C1S, C2S, C4S, P1S or inserts approved by manufacturer.

After connecting the handpiece to the cord, operate it for a few seconds until a constant spray of coolant is produced. The spray of water varies according to the power level and type of insert.

The insert mounted on the scaler handpiece reaches the correct operating frequency within a few tenths of a second after the device is activated. In order to allow proper syntonization, do not apply the tip to the tooth surface during this phase.

Handpieces with tips P1/P1S, C1/C1S and C4/C4S must not operate perpendicularly or head on to the tooth, but tangentially with slight lateral pressure, while the C2/C2S inserts can also work perpendicularly to the tooth surface. The P1/P1S insert must be used at a medium-low power level.

With any specific inserts for dry machining, operate at intervals of no more than 3 seconds.

7. INSERTS

C1 – (Code F680C2700), C1S – (Code 99926376)
Scaler Tip. Supragingival application.

C2 – (Code F680C2800), C2S – (Code 99926377)
Scaler Tip. Supragingival application.

C4 – (Code F680C9900), C4S – (Code 99926379)
Scaler Tip. Supragingival, incisors and neck of molars application.

E3 – (Code F680C6900)
Insert for the lateral thermal condensation of the gutta-percha.
Not available for handpiece for S-type tips.

E4 – (Code F680C6600)
Canal widening diamond-coated insert.
Not available for handpiece for S-type tips.

P1 – (Code F680C4400), P1S – (Code 99926378)
Scaler Tip / Prophylaxis. Supra and subgingival application, interproximal spaces and grooves.

P3 – (Code F680C8300)
Subgingival and root surface application, periodontal pocket irrigation with antibacterials.
Not available for handpiece for S-type tips.

R1 – (Code F680C8100)
R2 – (Code F680C8200)
R3 – (Code F680C7900)
RR – (Cod. F680C7700)
RL – (Cod. F680C7800)
Cavity preparation (small-scale interventions), particularly suitable for interdental cavities in front teeth and molars.
Not available for handpiece for S-type tips.

E1 – (Code F680C6800)
120° chuck for clamping endodontic files.
Not available for handpiece for S-type tips.

E2 – (Code F680C6700)
95° chuck for clamping endodontic files.
Not available for handpiece for S-type tips.

Endo wrench – (Code FR300R009)
Wrench for clamping the chuck to the handpiece and the files to the chuck.
Not available for handpiece for S-type tips.

8. USING INSTRUMENTS FOR ENDODONTIC THERAPY (NOT AVAILABLE FOR HANDPIECE FOR S-TYPE TIPS)

In units with the “ENDO” function, it is possible to use special inserts for endodontic therapy.
Set the ENDO functions using the control on the table.
Tighten the E1 (or E2) file-support chuck fully onto the handpiece using the corresponding wrench.
Always use a coolant to prevent the chuck from overheating.
Tighten the file in the chuck, making sure that the coloured notch remains visible, with the exception of the ISO 25 file (colour code red), which must be inserted fully.
Adjust the power to a minimum and increase it gradually, as needed, in any case not exceeding the limits specified in the table below:

ISO 15 file (colour code white)	max 25%
ISO 20 file (colour code yellow)	max 25%
ISO 25 file (colour code red)	max 50%
ISO 30 file (colour code blue)	max 100%
ISO 35 file (colour code green)	max 100%

Endosonore files: manufacturer Dentsply – Maillefer; Ref. A 012U

9. SETTING OPERATIONAL PARAMETERS

It is possible to adjust the speed, activate and adjust the spray or the lighting (if any) using the commands on the unit.
Refer to the unit instruction manual for operating parameter settings.

10. ILLUMINATION DEVICE

In models with the feature, the lighting in the surgical area operates in accordance with the provisions of the unit on which it is installed.
Refer to the unit user manual for information about the lighting device.
In order to replace the lighting element, unscrew the front part of the instrument and remove the tapered lighting element. When repositioning the new lighting element, be careful to respect the polarity. If the polarity is inverted, the light does not come on.

11. MAINTENANCE

If the handpiece is fed with liquid which might create encrustations, it is necessary to rinse the circuit with water after use.
To prevent it from becoming blocked, the insert must be removed after each treatment and before sterilization in an autoclave.
The manufacturer requires an annual check or overhaul of the device by authorised service assistance personnel.

12. CLEANING, DISINFECTION AND STERILISATION

Before disinfection, remove the inserts from the handpiece and the handpiece from the cord.
To maintain the level of hygiene, after each use and within a short time, clean, disinfect and sterilize the scaler.
Clean the coolant ducts by blowing air through using a syringe.
For external cleaning and/or disinfection, use gauze or cotton soaked in 70% v/v ethyl alcohol.
The inserts can be disinfected by immersing them in 70% v/v ethyl alcohol.
Sterilize the handpiece, the wrench, the inserts and the insert holder in a steam autoclave max 135 °C 220 kPa (2.2 bar) for 5 minutes (250 cycles tested – EN ISO 22374).

- Do not use ultrasound cleaners.
- Do not immerse the device in disinfectant or sterilizing liquids.
- Never sterilise the handpiece in a dry heat steriliser.
- Do not leave the device in the autoclave at the end of the cycle.
- Periodically check the autoclave according to the requirements of the manufacturer.
  Sterilization temperatures above the limit may damage the device.

13. REPAIRS AND OVERHAULS

Installation, overhaul, calibration and repair of the device must be performed exclusively by technical service assistance personnel authorised by the manufacturer.

14. MODE OF USE

The method of application of the device is intermittent. The operational cycle indicated respects the following times:

Type of Instrument	Operation (minutes)	Pause (minutes)
piezosteril 6	20	10
piezolight 6	20	10

15. ENVIRONMENTAL CONDITIONS FOR USE

- Ambient Temperature 10 ÷ 40 °C
- Relative Humidity 30 ÷ 75 %
- Atmospheric Pressure 700 ÷ 1060 hPa (700 ÷ 1060 mBar)

16. ENVIRONMENTAL CONDITIONS PERMITTED FOR TRANSPORT AND WAREHOUSING

- Ambient Temperature between -20 ÷ +70 °C
- Relative Humidity 10 ÷ 100 %
- Atmospheric Pressure 500 ÷ 1060 hPa (500 ÷ 1060 mBar)

17. TROUBLESHOOTING

FAULTS	PROBABLE CAUSES	INTERVENTION SUGGESTED
Insufficient power or no vibration.	The handpiece is not correctly inserted onto the cord.	Check connection.
	The power setting is at minimum.	Check the power setting on the unit.
	ENDO mode has been selected.	Check the operating mode setting.
	The insert is not properly tightened.	Tighten using the appropriate wrench.
	The insert is worn or deformed.	Replace the insert.
	The insert has micro fractures in the threaded area.	Replace the insert.
	The scaler is damaged.	Replace the handpiece.
	The cord is damaged.	Request technical support.
	The control panel is damaged.	Request technical support.
Insufficient water supply.	Water flow regulator closed.	Check the position of the flow regulator on the table or on the cord connector.
	Water duct blocked.	Make sure the hole in the insert is not blocked. Blow air through using the syringe if necessary.
	Cord blocked.	Request technical support.
	Water circuit not working.	Request technical support.
Inexistent or insufficient lighting.	Lighting element not mounted.	Check the presence of the lighting element.
	Lighting element with reverse polarity.	Check the polarity of the lighting element.
	Lighting element contacts dirty or oxidized.	Clean the lighting element contacts.
	Lighting element damaged.	Replace the lighting element.
	Cord damaged.	Request technical support.
	Control panel damaged.	Request technical support.

18. SCRAPPING

Scrapping the device must be carried out with respect for the laws in force for electrical and electronic equipment, according to the individual national laws.
The materials used for the manufacture are not harmful for human beings or animals that come into contact with or are exposed to them.

19. GUARANTEE CONDITIONS

The manufacturer provides the end user with a 12-month warranty, starting from the date of installation and, in any case, not exceeding 18 months from the invoice date, covering all operational faults, defects of materials or manufacture.

In case of justified complaints the manufacturer or the Authorised Repair Centre will proceed with the repair or substitution of the product free of charge.

To be able to make use of the free repair or substitution, it is an indispensable condition that, shipped together with the device, there is a proof of user's purchase document for the same device, which must include clearly legible references to the product, its serial number and date of purchase.

The guarantee expires when any damages and/or their consequences may be attributed to unsuitable procedures or modifications of the product performed by third parties not authorised by the manufacturer: that is, if non-original spare parts or components are used.

The recognition of any other claims from any origin whatsoever, in particular any requests for indemnification for damages or interest are excluded.

The manufacturer may not be held responsible for damages, or injuries and their respective consequences derived:

- From excessive wear.
- From connection of the instrument not compliant with the CE regulations.
- From improper tampering or maintenance performed by unauthorised personnel.
- From use of non-original accessories or spare parts.
- From the lack of observance of the instructions for use, for assembly or maintenance, or from improper use of the product.
- From unusual chemical, electrical or electronic influxes.
- From faulty connections (air water, electricity).

The guarantee does not cover the conductors such as the flexible “fibre optics”, nor any other elements made of synthetic materials.

20. MANUFACTURER

Manufactured by
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CEFLA sc - Via Selice Provinciale, 23/a - 40026 Imola (BO) Italy
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